

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference PA1906 PCT 1	<b>FOR FURTHER ACTION</b>	See item 4 below
International application No. PCT/US2004/038004	International filing date ( <i>day/month/year</i> ) 11 November 2004 (11.11.2004)	Priority date ( <i>day/month/year</i> ) 12 November 2003 (12.11.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant MEDTRONIC VASCULAR, INC.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- |                                     |              |   |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the report   |
| <input type="checkbox"/>            | Box No. II   | Priority  |
| <input checked="" type="checkbox"/> | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention  |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input checked="" type="checkbox"/> | Box No. VI   | Certain documents cited   |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application  |
| <input type="checkbox"/>            | Box No. VIII | Certain observations on the international application   |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 15 May 2006 (15.05.2006)
Facsimile No. +41 22 740 14 35	Authorized officer <div style="text-align: center; font-weight: bold;">Beate Giffo-Schmitt</div> Telephone No. +41 22 338 87 20

# PATENT COOPERATION TREATY

REC'D 06 MAY 2005

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From the  
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

26/5

see form PCT/ISA/220

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/US2004/038004

International filing date (day/month/year)  
11.11.2004

Priority date (day/month/year)  
12.11.2003

International Patent Classification (IPC) or both national classification and IPC  
A61F2/24

Applicant  
MEDTRONIC VASCULAR, INC.

### 1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

### 3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2004/038004

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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☐ in written format
    - ☐ in computer readable form
  - c. time of filing/furnishing:
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in computer readable form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2004/038004

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 22-24

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 22-24
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
  - the written form ☐ has not been furnished
  - ☐ does not comply with the standard
  - the computer readable form ☐ has not been furnished
  - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2004/038004

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**Box No. V Reasoned statement under Rule 43bis.1(a)(I) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	2-21
	No: Claims	1
Inventive step (IS)	Yes: Claims	2-21
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-21
	No: Claims	

2. Citations and explanations

**see separate sheet**

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**Box No. VI Certain documents cited**

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1. Certain published documents (Rules 43bis.1 and 70.10)

and /or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

**see form 210**

**Re Item III.**

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

**Re Item V.**

- 1 Reference is made to the following document:  
D1 : WO 02/096275 A (VIACOR, INCORPORATED) 5 December 2002 (2002-12-05)
- 2 **INDEPENDENT CLAIM 1**  
The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.  
Document D1 discloses (the references in parentheses applying to this document):  
A system for treating cardiac valve regurgitation comprising a delivery catheter (540), a treatment device disposed within a lumen of the delivery catheter (540) and a release mechanism (535) releasably connected to the treatment device and a push tube (545) slidably disposed within the delivery catheter for applying an axial force to the treatment device.
- 3 **DEPENDENT CLAIMS 2-12**  
The combination of the features of dependent claims 2-12 are neither known from, nor rendered obvious by, the available prior art. The reasons are as follows:  
There is no document disclosing a treatment device as described in claim 2 (see following paragraph concerning independent claim 13).
- 4 **INDEPENDENT CLAIM 13**
  - 4.1 Document D1, which is considered to represent the most relevant state of the art, discloses (the references in parentheses applying to this document):  
A device (500) for treating cardiac valve regurgitation comprising a tube (535) including a lumen.  
From this, the subject-matter of independent claim 13 differs in that the device comprises a locking mechanism disposed upon an outer surface of the tubular member

and a compression device carried on the tubular member, wherein the compression device is transformable to a compression configuration responsive to application of an axial force and is lockable in the compression configuration with the locking mechanism.

**4.2 The subject-matter of claim 13 is therefore novel (Article 33(2) PCT)**

The problem to be solved by the present invention may be regarded as:

To apply a low level of compression to the wall of the coronary sinus in order to affect a change in the mitral valve annulus sufficient to reduce or eliminate valve regurgitation and reduce the risks of damaging the wall of the coronary sinus.

**4.3 The solution to this problem proposed in claim 13 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:**  
No document of the existing prior art discloses a device with a locking mechanism disposed upon an outer surface of the tubular member and a compression device carried on the tubular member, wherein the compression device is transformable to a compression configuration responsive to application of an axial force and is lockable in the compression configuration with the locking mechanism.

**4.4 Claims 14-21 are dependent on claim 13 and as such also meet the requirements of the PCT with respect to novelty and inventive step.**